



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------|------------------|
| 10/670,819 | 09/24/2003 | Gerald Fredrickson | 12013/49401 | 7313 |
| 26646 | 7590 | 08/02/2005 | EXAMINER | |
| KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004 | | | PARKER, FREDERICK JOHN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1762 | |

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,819

Applicant(s)

FREDRICKSON, GERALD

Examiner

Frederick J. Parker

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/5/05 (IDS).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/5/05.

- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 5/3-2/11/05
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Prosecution on the merits of this application is reopened on claims 1-13 considered unpatentable for the reasons indicated below:

The rejections under 35 USC 102 and 103, as follows:

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3,6-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by CritiTech website dated 6/15/02.

CritiTech website discloses coating “levitated” stents in a chamber and spraying material (polymer or drugs (a “therapeutic agent”)) dissolved in a supercritical CO₂ stream in close proximity to the stents. The method is an extension of previously described CritiTech technology which requires ultrasonic-based nozzles to produce a discrete range of nanoparticles (p.4). Heating and cooling of supercritical CO₂ is inherent in the process.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1762

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4-5,9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over CritiTech website.

The reference is cited for the same reasons previously discussed, which are incorporated herein.

As to claims 4-5, the rate of ultrasonic vibration is not expressly stated but would have been an obvious process variable determined by routine experimentation by the skilled artisan to provide the requisite discrete sized nanoparticles in a narrow particle size range to form a desired coating thickness and uniformity.

As to claim 9, the number of stents is not limited and would have been only dependent upon the scale of the apparatus, which does not patentably distinguish over the prior art, MPEP 2144.04 IVA.

As to claim 10, the type of stents is not limited by the reference and therefore would have encompassed flexible stents because of the expectation of successful coating.

As to claim 11, the rate of coating would have been determined by routine experimentation to efficiently apply a coating of desired thickness to a specific substrate for a specific drug dosage.

Art Unit: 1762

As to claims 12-13, the description of CritiTech is essentially that of Applicants' "hurricane" and is therefore considered to be the same or functionally equivalent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out the process disclosed by CritiTech and optimize conventional process parameters, such as rate of ultrasonic vibration or coating rate, stent type or numbers coated, etc because such parameters would have been obvious process variations to produce coated stents formed of nanoparticles in a narrow particle size range, which translates into more even, uniform coatings of stents with coatings containing drugs/ therapeutic agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick J. Parker whose telephone number is 571/ 272-1426. The examiner can normally be reached on Mon-Thur. 6:15am -3:45pm, and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571/272-1423. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

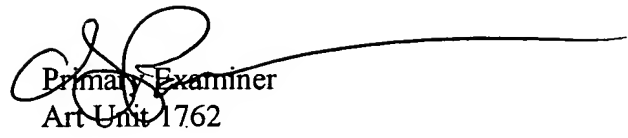
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick J. Parker

Application/Control Number: 10/670,819

Page 5

Art Unit: 1762


Primary Examiner
Art Unit 1762

fjp